

- 9-3
11. (New) The method of claim 10, wherein the symptom is selected from the group consisting of: arthritis in a foreleg or hind leg joint, joint stiffening, destruction of joint cartilage or bone, lymphocyte infiltration of joint cartilage or bone and production of type II collagen autoantibody. --

REMARKS

These remarks are in response to the Office Action mailed January 12, 2000. Claim 1 is pending. New claims 2 to 11 have been added. Thus, upon entry of the amendment, claims 1 to 11 are pending. Applicant respectfully requests reconsideration of the present application.

Regarding the Amendments

Claim 1 has been amended to insert the term "BALB/c." The amendment defines the claimed subject matter with greater particularity and is supported by the specification, for example, at page 3, paragraph 1, which discloses that the SKG mouse was from a BALB/c colony. The amendment to delete the phrases "having the character of" and "the character being derived from" was made in response to the Examiner's concern with the term "character." The amendment to insert the phrase "that develops" was made to more clearly indicate the claimed subject matter, *i.e.*, a BALB/c mouse "that develops natural onset of autoimmune arthritis." The amendment to insert the phrase "mouse strain denoted" was made to indicate that the recitation of the term "SKG," is used to denote a BALB/c mouse strain that develops natural onset of autoimmune arthritis. Accordingly, the amendments to claim 1 are supported by the specification or address informalities.

In sum, the amendments to claim 1 are supported by the specification or were made to address informalities and, therefore, do not add new matter. Accordingly, Applicant respectfully requests entry of the amendments.

Regarding the New Claims

Support for new claims 2 to 11 can be found throughout the specification. In particular, claim 2, directed to a mouse of claim 1 where the autoimmune arthritis comprises rheumatoid arthritis, is supported, for example, at page 3, paragraph 3. Claims 3 to 5, each of which recite a further characteristic of the mouse of claim 1, are supported, for example, at page 4, paragraphs 2-5, and at page 3, paragraph 2. Claims 6 to 9, directed to methods of producing

SKG BALB/c mice and mice that develop natural onset of autoimmune arthritis, are supported, for example, at page 5, paragraph 1, and at page 4, paragraph 5. Claims 10 and 11, directed to methods of identifying a therapy that decreases a symptom of rheumatoid arthritis, are supported, for example, at page 2, paragraph 2; at page 3, paragraph 2; and at page 4, paragraphs 1-4. Thus, claims 2 to 11 are supported by the specification.

In sum, new claims 2 to 11 are supported by the specification and no new matter has been added. Accordingly, Applicant respectfully requests entry of new claims 2 to 11.

Regarding the Priority Application

The Examiner recommends that reference to the priority claim be made in the first line of the specification. As set forth above, Applicant has amended the specification to insert the priority information for the subject application.

Regarding the Specification

The specification stands objected to due to the placement of the Brief Description of the Drawings after the Detailed Description of the Invention. As set forth above, Applicant has amended the specification to insert the Brief Description of the Drawings immediately before the Description of the Invention. Accordingly, in view of the amendment, Applicant respectfully requests that the objection to the specification be withdrawn.

Regarding the Deposit Requirement

The Examiner indicates that a deposit is required in accordance with 37 CFR §1.801-1.809 "because the claimed invention is directed to a particular strain of mouse, and may not be made in a reproducible manner." Applicant respectfully requests that the deposit requirement be held in abeyance until such time as allowable subject matter is indicated, after which Applicant will comply with the deposit requirements under 37 CFR §1.801-1.809.

I. REJECTION UNDER 35 U.S.C. §101

The rejection of claim 1 under 35 U.S.C. §101 as unpatentable because the claimed subject matter is allegedly non-statutory is respectfully traversed. The Office Action alleges that "... the SKG mouse has not been altered by the hand of man in any way, and is a naturally

occurring animal. Therefore, the strain of mouse of claim 1 is considered to be directed to non-statutory subject matter" (see page 6 of the Office Action).

Applicant submits that claim 1, as amended, directed to a BALB/c mouse strain having natural onset of autoimmune arthritis, is directed to statutory subject matter. First of all, the SKG mouse is from a BALB/c strain of mouse, an albino, inbred strain originally developed by the hand of man and which does not occur in nature (see, e.g., www.jax.org). Therefore, as the SKG mouse is from an inbred strain of mouse produced by the hand of man that does not exist in nature, the SKG mouse is not a naturally occurring animal. Accordingly, claim 1, as amended, is directed to statutory subject matter.

Secondly, Applicant respectfully directs the Examiner's attention to M.P.E.P. §2105, which outlines the tests set forth by the court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980) for determining statutory subject matter. In particular, under section "(D)," the M.P.E.P. states, in reference to *Diamond v. Chakrabarty*, that "[T]he production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties or combinations, whether by hand labor or by machinery" [emphasis added] is a "manufacture" under 35 U.S.C. 101. By analogy, the SKG mouse is from the albino BALB/c mouse strain, a mouse strain given "new forms, qualities, and properties" by the hand of man. Thus, as the SKG mouse itself has new properties and was obtained from a BALB/c strain given "new forms, qualities, and properties," the SKG mouse is statutory subject matter.

Applicant also respectfully directs the Examiner's attention to the claims of U.S. Patent No. 6,040,495, submitted herewith as Exhibit A, which are directed to a particular type of NS:Hr/ICR hairless mouse susceptible to *Helicobacter pylori* infection. The hairless mice susceptible to *Helicobacter pylori* infection of the '495 patent were obtained from breeding a male hairless ICR mouse with a female hairless mouse (see column 2, lines 10-29). The inventors of the '495 patent then investigated the character of the NS:Hr/ICR hairless mouse and found that *Helicobacter pylori* can easily infect the mouse (see column 2, lines 30-37). Thus, the NS:Hr/ICR hairless mouse susceptible to *Helicobacter pylori* of the '495 patent has a special character as an experimental animal apart from hairless mice in general and, therefore appears to be a mutant offspring of hairless mice (see, for example, column 2, lines 51-55; and column 3, lines 12-18).

By analogy to the NS:Hr/ICR hairless mouse susceptible to *Helicobacter pylori* of the '495 patent identified from a breeding of two hairless mice that do not occur in nature, the SKG mouse having natural onset of autoimmune arthritis of claim 1 was identified from a breeding of

two BALB/c mice that do not occur in nature (see the specification, page 4, last paragraph). Accordingly, as the SKG mouse of claim 1 having natural onset of autoimmune arthritis is analogous to the patented NS:Hr/ICR hairless mouse susceptible to *Helicobacter pylori*, in that it was obtained from an inbred mouse strain that does not occur in nature and appears to be a mutant, the SKG mouse, like the NS:Hr/ICR hairless mouse, is patentable subject matter.

II. REJECTION UNDER 35 U.S.C. §112

The rejection of claim 1 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is respectfully traversed. The Office Action alleges that claim 1 is indefinite for the recitation of "the character," "autoimmune arthritis," and "the character being derived from the SKG strain."

Applicant submits that claim 1, as originally filed, is clear and definite. Nevertheless, in order to further prosecution of the subject application, claim 1, as amended, no longer recites the phrases "the character," and "the character being derived from the SKG strain." Accordingly, the grounds for rejection due to the recitation of these phrases is moot.

As to the meaning of the term "autoimmune arthritis," Applicant submits that in view of the specification the meaning of this term would be clear to the skilled artisan. In this regard, the specification discloses physiological and morphological features that are characteristic of "autoimmune arthritis" in the SKG mouse, any one of which is a characteristic of "autoimmune arthritis." In particular, for example, the specification discloses that: "(1) it pathohistologically resembles human rheumatoid arthritis in its chronic progression from the appearance of pannus to the inflammatory destruction of joint cartilage and bone accompanied by lymphocyte infiltration"; "(2) clinically, it resembles human rheumatoid arthritis in that the small and large joints of the forelegs and hind legs are affected symmetrically, and in that the lesions chronically progress and finally lead to joint stiffening"; and "(3) it resembles human rheumatoid arthritis in that rheumatoid factor, autoantibody against type II collagen specific for joints, and hypergammaglobulinemia develops highly frequently in the mouse of the invention" (see page 3, paragraph 4, to page 4, paragraph 3). Thus, in view of the specification, the skilled artisan would understand that "autoimmune arthritis" has one or more characteristics that resemble human rheumatoid arthritis. As such, the meaning of "autoimmune arthritis" is clear and, therefore, one skilled in the art would understand the metes and bounds of claim 1. Accordingly, claim 1, as

amended, is clear and definite under 35 U.S.C. §112, second paragraph and Applicant respectfully requests withdrawal of the rejection.

III. REJECTIONS UNDER 35 U.S.C. §102(b)

The rejection of claim 1 under 35 U.S.C. §102(b) as allegedly anticipated by Nakamura *et al.* (*Arthritis and Rheumatism* 34:171 (1991)), Hang *et al.* (*J. Exp. Med.* 1982), Bouvet *et al.* (*Arthritis and Rheumatism* 33:1716 (1990)) and Nordling *et al.* (*Arthritis and Rheumatism* 35:717 (1992)) is respectfully traversed. The Office Action indicates that Nakamura *et al.* describe "male New Zealand Black/KN mice that develop a natural onset of immune-mediated arthritis"; that Hang *et al.* describe "MRL/1 mice which also develop a natural (spontaneous) onset of immune-mediated arthritis"; that Bouvet *et al.* describe "Biozzi mice which also develop a natural (spontaneous) onset of immune-mediated arthritis"; and that Nordlin *et al.* describe "DBA/1 mice which also develop a natural (spontaneous) onset of immune-mediated arthritis." Therefore, each of Nakamura *et al.* (1991), Hang *et al.* (1982), Bouvet *et al.* (1990) and Nordling *et al.* (1992) allegedly anticipate claim 1.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration (In re Spada, 15 USPQ 2d 1655 (Fed. Cir. 1990); In re Bond, 15 USPQ 2d 1566 (Fed. Cir. 1990)).

As set forth above, claim 1, as amended, recites that the SKG mouse is a BALB/c mouse strain. In contrast, neither Nakamura *et al.* (1991), Hang *et al.* (1982), Bouvet *et al.* (1990) nor Nordling *et al.* (1992) describe a BALB/c mouse strain. Rather, as acknowledged in the Office Action, Nakamura *et al.* describe New Zealand Black/KN mice; Hang *et al.* describe MRL/1 mice; Bouvet *et al.* describe Biozzi mice; and Nordling *et al.* describe DBA/1 mice. Thus, as the SKG mouse strain of claim 1 is distinct from the mouse strains described by each of Nakamura *et al.* (1991), Hang *et al.* (1982), Bouvet *et al.* (1990) and Nordling *et al.* (1992), claim 1 cannot be anticipated by any of these cited references. Accordingly, Applicant respectfully requests that the rejections under 35 U.S.C. §102(b) be withdrawn.

CONCLUSION

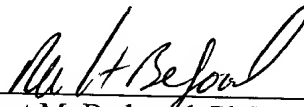
In summary, for the reasons set forth herein, Applicant maintains that claims 1 to 11 clearly and patentably define the invention, respectfully requests that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully requests the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 678-5070. Included herewith are a petition for an extension of time until May 12, 2000, to file this Response and the required fee. Please charge any additional fees, or make any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

Date: _____

5/12/00



Robert M. Bedgood, Ph.D.
Reg. No. 43,488

Fish & Richardson P.C.
4350 La Jolla Village Drive, Suite 500
San Diego, CA 92122
Telephone: (858) 678-5070
Facsimile: (858) 678-5099